UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,445	10/04/2006	Christer Nordstedt	GRT/117-580	6580

23117 7590 06/07/2007

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER
MACFARLANE, STACEY NEE

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
06/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,445	NORDSTEDT ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,20,21,28-33,37-55 and 59-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9,11,20,21,28-33,37-55 and 59-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, 11, 20,21, 28-33, 51-59, and 64-68, drawn to a human antibody, which has a heavy chain CDR3 region, that binds to the C-terminal domain of Apolipoprotein E in the presence of VLDL, and binds to human plaques.

Group 2, claim(s) 37-41, drawn to an antibody or antibody fragment.

Group 3, claim(s) 42-46, drawn to an antibody or antibody fragment.

Group 4, claim(s) 47-50, drawn to an antibody or antibody fragment.

Group 5, claim(s) 60-63, drawn to method of treating a subject comprising administering the antibody of Group 1.

Group 6, claim(s) 69, drawn to in vitro methods for detecting ApoE-CTD in a sample comprising contacting said sample with the antibody of Group 1.

The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the single general inventive concept that permeates the groups is an antibody. Groups 1, 5 and 6 pertain to the same antibody which has a heavy chain CDR3 region, binds to the C-terminal domain of Apolipoprotein E in the presence of VLDL, and binds to human plaques,

however, the antibodies of Groups 2, 3, and 4, as claimed, are not related to this product. Therefore the Unity of Invention is broken between the groups. Furthermore, the expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. The following reference teaches the general inventive concept of Groups 1, 5, and 6, a human ApoE c-terminal domain antibodies that binds to human plaques and methods of use (Cho et al. Journal of Neuropathology and Experimental Neurology 60(4): 342-349). Therefore the prior art recites the common technical feature of Groups 1, 5 and 6, thus, there is no special technical feature over the prior art and these groups also lack Unity of Invention under PCT Rule 13.1.

Species Election

This application contains claims directed to the following patentably distinct species:

Group 1:

(Claim 1 part (ii b) and Claim 2) Elect a single CDR3 region from the following or a single specific combination thereof: SEQ ID NO: 512, SEQ ID NO: 513, SEQ ID NO: 514, SEQ ID NO: 515, SEQ ID NO: 516 or SEQ ID NO: 517. And further requiring an election for Claim 1 part (ii c) and Claim 7 of a single CDR3 region from the following: SEQ ID NO: 29, SEQ ID NO: 47, SEQ ID NO: 50, SEQ ID NO: 53, SEQ ID NO: 56, SEQ ID NO: 59, SEQ ID NO: 62, SEQ ID NO: 65, SEQ ID NO: 68, SEQ ID NO: 71, SEQ ID NO: 74, SEQ ID NO: 77, SEQ ID NO: 80, SEQ ID NO: 83, SEQ ID NO: 86 or SEQ ID NO: 89.

(Claim 5) Elect one of the following sequences, which further limit the election of Claim 1: SEQ ID NO: 207, SEQ ID NO: 208, SEQ ID NO: 209, SEQ ID NO: 210, SEQ ID NO: 320, SEQ ID NO: 321, SEQ ID NO: 322, SEQ ID NO: 323, SEQ ID NO: 373, SEQ ID NO: 374, SEQ ID NO: 375, SEQ ID NO: 376, SEQ ID NO: 485, SEQ ID NO: 486, SEQ ID NO: 487, SEQ ID NO: 488 or SEQ ID NO: 489.

(Claim 6) Elect one of the following sequences further limiting the election of Claim 5: SEQ ID NO: 207, SEQ ID NO: 208, SEQ ID NO: 209, SEQ ID NO: 320, SEQ ID NO: 321, SEQ ID NO: 322, or SEQ ID NO: 373.

(Claim 8) Elect one of the following sequences further limiting the election of Claim 7: SEQ ID NO: 50, SEQ ID NO: 68; SEQ ID NO: 74 or SEQ ID NO: 80.

(Claim 33) Elect a single species or specific combination thereof from: SEQ ID NO: 517, SEQ ID NO: 518, SEQ ID NO: 519, or SEQ ID NO: 520.

Group 2:

(Claim 37) Elect one of the following: SEQ ID NOs: 207, 209, or 210.

(Claims 38 and 39) Elect either an antibody comprising SEQ ID NOs: 226, 252, and 275 OR an antibody comprising SEQ ID NOs: 218, 34, and 268.

(Claim 40) Elect an antibody fragment comprising SEQ ID NO: 317, 318 or 319, which further limits the election of Claim 37.

(Claim 41) Elect an antibody fragment comprising SEQ ID NO: 43, 295, 294 or 304, which further limits the election of Claim 38.

Group 3:

(Claim 42) Elect one of the following: SEQ ID NO: 320, 322 or 323.

(Claim 43) Elect an antibody fragment comprising SEQ ID NO: 93, 333 and 341 or an antibody fragment comprising SEQ ID NO: 325 and 333, which further limits the election of parent Claim 42.

(Claim 44) Elect one of the following: (1) an antibody fragment comprising SEQ ID NO: 320 and SEQ ID NOs: 93, 33, and 341; or (2) an antibody fragment comprising SEQ ID NO: 320 and SEQ ID NOs: 325, 333, and 341; or (3) an antibody fragment comprising SEQ ID NO: 322 and SEQ ID NOs: 326, 334, and 341; or (4) an antibody fragment comprising SEQ ID NO: 322 and SEQ ID NOs: 93, 333, and 341; or (5) an antibody fragment comprising SEQ ID NO: 322 and SEQ ID NOs: 325, 333, and 341; or (6) an antibody fragment comprising SEQ ID NO: 323 and SEQ ID NOs: 93, 33, and 341.

(Claim 45) Elect an antibody fragment comprising SEQ ID NO: 369, 370, 371, or 372, which further limits the election of Claim 42.

(Claim 46) Elect an antibody fragment comprising SEQ ID NO: 347, 348, 357, or 362, which further limits the election of Claim 43.

Group 4:

(Claim 48) Elect either an antibody comprising SEQ ID NOs: 391,382, and 378, or an antibody comprising SEQ ID NOs: 394,386, and 378.

(Claim 50) Elect either comprising SEQ ID NO: 406 or comprising SEQ ID NO: 418.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no generic claims for Groups 1-3, as all independent claims require election of species. Claim 47 is generic to Group 4.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on Monday-Thursday 6:30AM-4:00 PM & ALT. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MARY MOSHER
SUPERVISORY PATENT EXAMINER
6-4-07